Complete Summary

GUIDELINE TITLE

Smallpox vaccine.

BIBLIOGRAPHIC SOURCE(S)

American Academy of Pediatrics. Smallpox vaccine. Pediatrics 2002 Oct;110(4):841-5. [18 references] PubMed

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Smallpox

GUIDELINE CATEGORY

Management
Prevention

CLINICAL SPECIALTY

Emergency Medicine
Family Practice
Infectious Diseases
Internal Medicine
Pediatrics
Preventive Medicine

INTENDED USERS

Advanced Practice Nurses
Nurses
Physician Assistants
Physicians
Public Health Departments

GUIDELINE OBJECTIVE(S)

- To review the current status of smallpox vaccine, the adverse effects that were associated with smallpox vaccine in the past, and the major proposals for vaccine use
- To provide a rationale for a policy based on the ring vaccination strategy recommended by the Centers for Disease Control and Prevention

TARGET POPULATION

Individuals exposed to smallpox

INTERVENTIONS AND PRACTICES CONSIDERED

Strategies for Smallpox Immunization

1. Mass immunization (considered but not recommended)
2. Voluntary immunization (considered but not recommended)
3. Ring vaccination (i.e., surveillance and containment)

MAJOR OUTCOMES CONSIDERED

- Mortality rates from smallpox
- Smallpox prevention rates
- Rate of complications and adverse effects from smallpox vaccination

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Not stated

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not stated

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

1. At present, the American Academy of Pediatrics (AAP) supports the ring vaccination approach to contain smallpox cases that might develop as a result of bioterrorism. (A description of this approach is provided below.)
2. Ongoing reassessment of the risk of smallpox as a bioterrorism agent is critical; any change in that assessment should be shared with public health authorities.
3. Ongoing attempts to develop a safer and more effective smallpox vaccine should continue and should be supported. Smallpox vaccines, including those presently available and those developed in the future, should be evaluated for safety and immunogenicity in children as well as adults.
4. Health care professionals throughout the country should be educated regarding identification of smallpox.

5. The Centers for Disease Control and Prevention (CDC) and regional and local public health authorities should have a plan in place to respond immediately to a suspected or confirmed case of smallpox.
6. The public should be educated that the concept of ring vaccination means that some individuals will be immunized according to a mandatory (no nonmedical exemptions) protocol and that quarantine may have to be used (including, possibly, separating family members).
7. The public should be educated about the possible serious adverse effects of smallpox immunization, especially for children, because surveillance studies demonstrate that they have a higher incidence of adverse effects.

Recommended Strategy: Ring Vaccination (Surveillance and Containment)

The AAP supports the current CDC recommendation of the strategy known as ring vaccination, also referred to as surveillance and containment. Using this approach, if smallpox were introduced in an act of terrorism, infected patients would be isolated. Contacts of infected individuals as well as their contacts would then be identified and immunized by specially trained teams of health care professionals. This strategy can control a localized outbreak with minimal exposure of vulnerable populations to the complications of immunization. The ring strategy is based on the knowledge that vaccination can prevent or ameliorate disease severity if given within 3 to 4 days of initial exposure and can decrease symptoms if given within the first week of exposure.

Immunizing and monitoring a ring of people around each infected individual and his or her contacts would help protect those at the greatest risk of contracting the disease and form a buffer of immune individuals to prevent the spread of disease. AAP´s rationale as to why this strategy would be more desirable than a pre-event mass immunization campaign is provided in the original guideline document.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The guideline is partly adapted from the Centers for Disease Control and Prevention guideline on smallpox. Other types of evidence supporting the recommendation are not specifically stated.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Using the strategy of ring vaccination, if smallpox were introduced in an act of terrorism, infected patients would be isolated. Contacts of infected individuals as well as their contacts would then be identified and immunized by specially

trained teams of health care professionals. This strategy can control a localized outbreak with minimal exposure of vulnerable populations to the complications of immunization. The ring strategy is based on the knowledge that vaccination can prevent or ameliorate disease severity if given within 3 to 4 days of initial exposure and can decrease symptoms if given within the first week of exposure.

- Immunizing and monitoring a ring of people around each infected individual and his or her contacts would help protect those at the greatest risk of contracting the disease and form a buffer of immune individuals to prevent the spread of disease. This strategy would be more desirable than a pre-event mass immunization campaign. (See the original guideline document for an extensive discussion of the rationale.)

POTENTIAL HARMS

- Immunization causes a local infection that is pruritic and uncomfortable. Fever, malaise, and regional lymphadenitis often occur about a week after immunization. The site of immunization develops a papule that matures into a pustule and then a scab that separates by about the third week after immunization. Reimmunization typically causes a milder lesion that develops more quickly. Occasionally, satellite or distant pustules develop when a vaccine recipient scratches the pustule and autoinoculates the virus at another site.
- Severe complications of immunization include death, postvaccinal encephalitis, progressive vaccinia, eczema vaccinatum, generalized rash, and accidental inoculation to the face, eye, or other sites (see Table 1 in the original guideline document for risks of death and complications from smallpox immunization per million vaccine recipients).

Subgroups Most likely to be Harmed:

- Smallpox vaccine has been known for decades to produce significant adverse effects, especially in immunocompromised persons. In patients with chronic skin conditions, smallpox vaccine can cause a severe, sometimes fatal dermatologic involvement termed "eczema vaccinatum." The list of conditions that place patients at risk of eczema vaccinatum is long and includes most disorders that disrupt epidermal integrity. Atopic dermatitis is the most common disorder associated with severe eczema vaccinatum, and people with this disorder may be susceptible even if the skin disorder is in remission. Even unimmunized susceptible individuals can have such reactions if the virus spreads to them from those who have been immunized.
- Smallpox vaccine is not recommended for people with eczema or other exfoliative skin disorders, for pregnant women, or for people with immunodeficiencies, whether primary or secondary. Atopic dermatitis, a genetically based immune abnormality, occurs within the first 5 years of life and affects 15% of the population.

QUALIFYING STATEMENTS

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The recommendations in this statement do not indicate an exclusive course of treatment or serve as a standard of medical care. Variations, taking into account individual circumstances, may be appropriate.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness
Safety

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

American Academy of Pediatrics. Smallpox vaccine. Pediatrics 2002 Oct;110(4):841-5. [18 references] PubMed

ADAPTATION

The guideline was partially adapted from the Centers for Disease Control and Prevention guideline on smallpox: Centers for Disease Control and Prevention. Vaccinia (smallpox) vaccine: recommendations of the Advisory Committee on Immunization Practices (ACIP), 2001. MMWR Recomm Rep 2001 Jun 22;50(RR-10):1-25.

DATE RELEASED

2002 Sep

GUIDELINE DEVELOPER(S)

American Academy of Pediatrics - Medical Specialty Society

SOURCE(S) OF FUNDING

American Academy of Pediatrics

GUIDELINE COMMITTEE

Committee on Infectious Diseases

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

American Academy of Pediatrics (AAP) Policies are reviewed every 3 years by the authoring body, at which time a recommendation is made that the policy be retired, revised, or reaffirmed without change. Until the Board of Directors approves a revision or reaffirmation, or retires a statement, the current policy remains in effect.

GUIDELINE AVAILABILITY

Electronic copies: Available from the American Academy of Pediatrics (AAP) Policy Web site.

Print copies: Available from AAP, 141 Northwest Point Blvd., P.O. Box 927, Elk Grove Village, IL 60009-0927.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on January 28, 2003. The information was verified by the guideline developer on April 16, 2003.

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